

UNITED STATES AIR FORCE RESEARCH LABORATORY

TESTING AND EVALUATION OF THE OHMEDA, INC., MODEL 3800 PULSE OXIMETER

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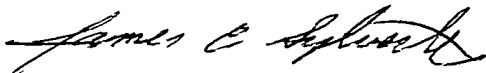
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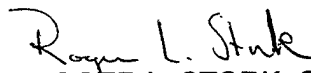
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TESTING AND EVALUATION OF THE OHMEDA, INC., MODEL 3800 PULSE OXIMETER

BACKGROUND

The Ohmeda company requested Aeromedical Research's participation in evaluating and approving their model 3800, pulse oximeter for use on board USAF aeromedical evacuation aircraft. Specific components of the model 3800, pulse oximeter that underwent the evaluation process included the model 3800, pulse oximeter basic unit and the clip tip sensor (P/N 6051-0000-112). All components of the model 3800, pulse oximeter were tested for air worthiness. Throughout this report the term Equipment Under Test (EUT) refers to the model 3800, pulse oximeter.

DESCRIPTION

The EUT is a noninvasive, arterial oxygen saturation and pulse monitor. The unit operates on 100/120 VAC / 60 Hz and an internal rechargeable battery pack (Figure 1). The unit weighs approximately 2.23 Kg or 4.92 lb. and is 9.53 in. W. X 3.7 in. H. X 8.86 in. D.

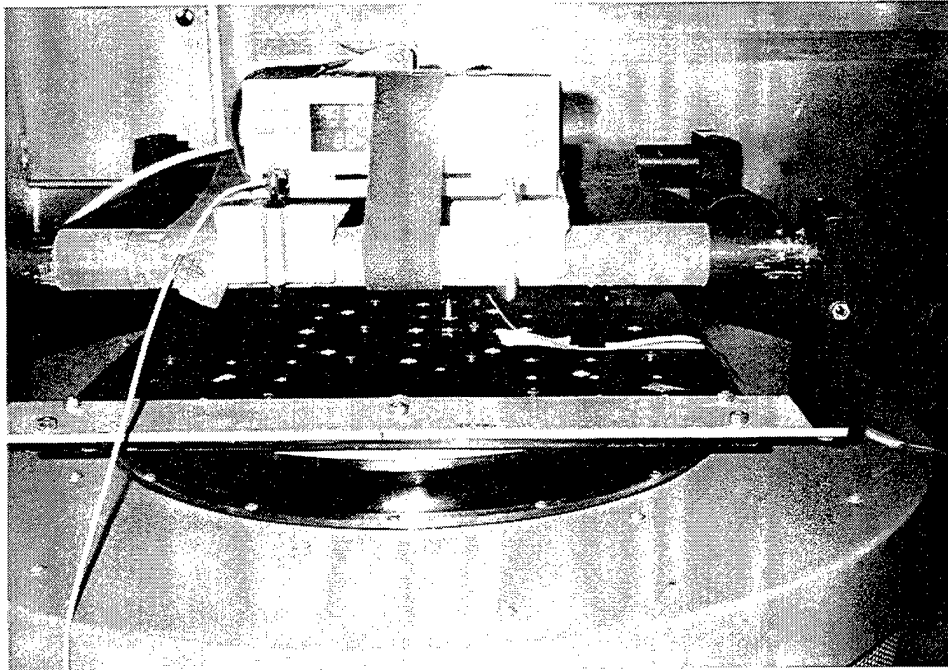


Figure 1. Ohmeda 3800, Pulse Oximeter

PROCEDURES

Test methods and performance criteria were derived from nationally recognized performance guidelines (1 & 5), various military standards (2-4 & 6-8), and manufacturer's literature (9). The Aeromedical Research Procedures Guide describes additional safety and human interface issues to be considered during equipment testing (10). A test setup and performance check were developed specific to this EUT to verify its proper functioning under various testing conditions. All tests are conducted by Aeromedical Research personnel assigned to the Systems Research Branch (HEPR), Flight Stress Protection Division, Air Force Research Laboratory, Brooks AFB, TX., unless otherwise noted.

The EUT was subjected to various laboratory and inflight tests to observe and evaluate its performance under anticipated operational conditions.

1. Initial Inspection
2. Vibration
3. Electromagnetic Interference (EMI)
4. Thermal/ Humidity Environmental Conditions, encompassing:
 - a. Hot Operation
 - b. Cold Operation
 - c. Humidity Operation
 - d. Hot Temperature Storage
 - e. Cold Temperature Storage
5. Hypobaric Conditions
 - a. Cabin Pressure/Altitude
 - b. Rapid Decompression to Ambient Pressure
6. Airborne Performance

INITIAL INSPECTION AND TEST PREPARATION

- a. The EUT was inspected for quality of workmanship, production techniques and pre-existing damage.

b. The EUT was checked to ensure it met safety requirements and operating characteristics established in National Fire Protection Agency (NFPA) 99 (1); AFI 41-203, Electrical Shock Hazards (2); and AFI 41-201, Equipment Management in Hospitals (3). Ground resistance and leakage current measurements were made at 115 VAC/60 Hz and 115 VAC/400 Hz.

c. The EUT was examined to ensure it met basic requirements for human factors design as outlined in MIL-STD 1472 (4).

d. A test setup and performance check were developed to evaluate the EUT's operation in accordance with manufacturer/customer specifications throughout the various testing conditions.

TEST SETUP

The EUT was placed on a level surface, AC power cord plugged into 115 VAC/60 Hz power or use internal battery, turn unit on, clip tip sensor connected to SpO₂ simulator.

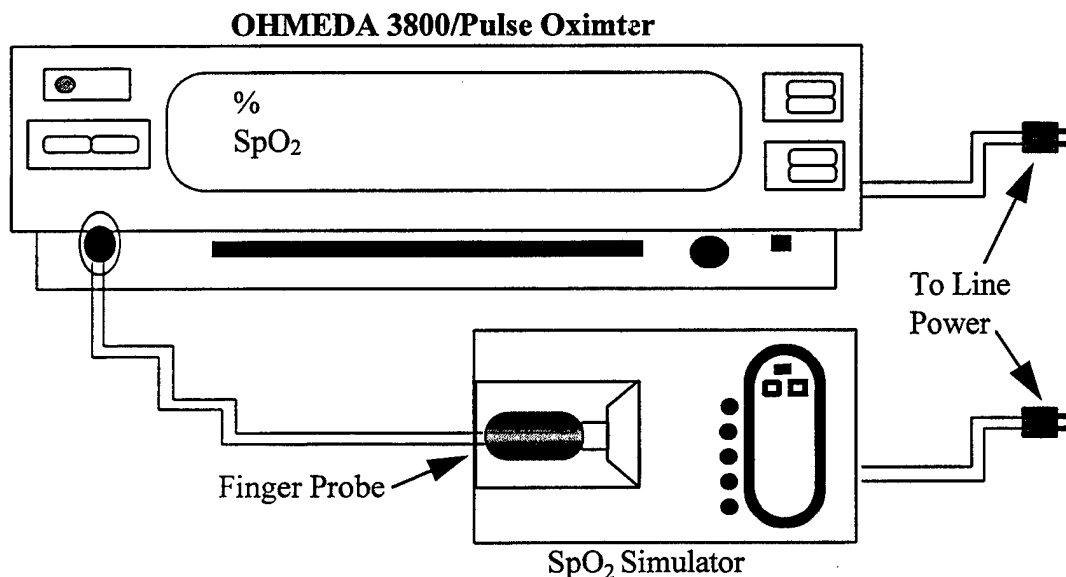


Figure 2. Test Setup

PERFORMANCE CHECK

The following performance check was used to validate the function of the EUT during each of the following test conditions:

Connect clip tip sensor to receptacle on front of EUT. Plug EUT into 115 VAC/60 Hz power source or use internal battery. Attach clip tip sensor to SpO₂ simulator. Set SpO₂ simulator to 98% oxygen saturation with a pulse rate of 60 bpm.

Battery Performance was assessed as outlined in Ohmeda, Inc., Operators Manual (9).

VIBRATION

Vibration testing is critical to determine "the resistance of equipment to vibrational stresses expected in its shipment and application environments" (6). Testing was conducted on a Unholtz-Dickey Corporation Vibration Test System, amplifier model SA30 and shaker model R16W. This testing involved a set of operational tests performed along each of three axes - X, Y, and Z. The EUT's components were mounted on a NATO litter segment on the vibration table as it would be secured in the aircraft (Figure 3). They were subjected to vibration curves with similar intensities and durations as those derived from MIL-STD-810E, Category 10, Figures 514.4-16 and 514.4-17 (Figure 4).

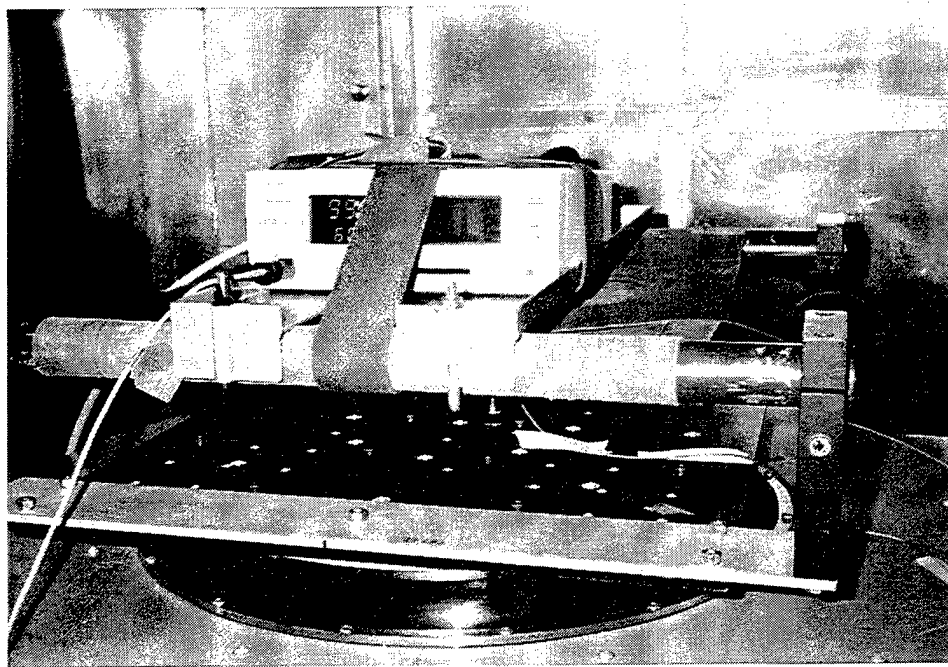


Figure 3. Vibration Table Mounting

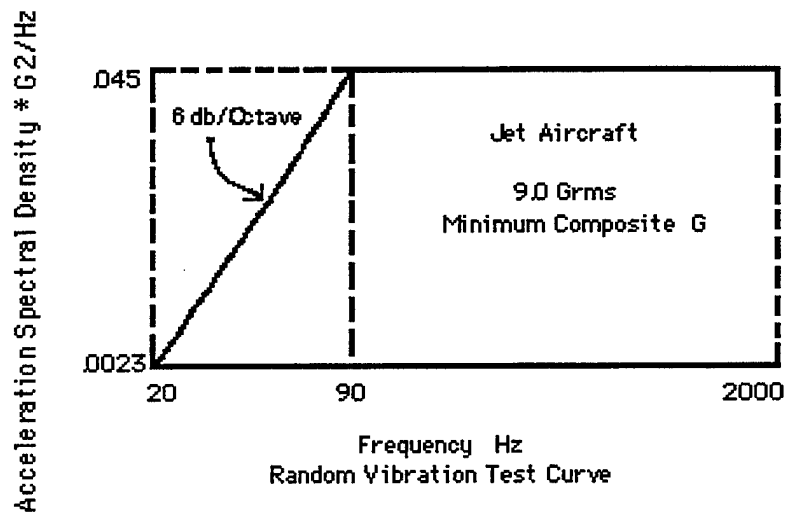
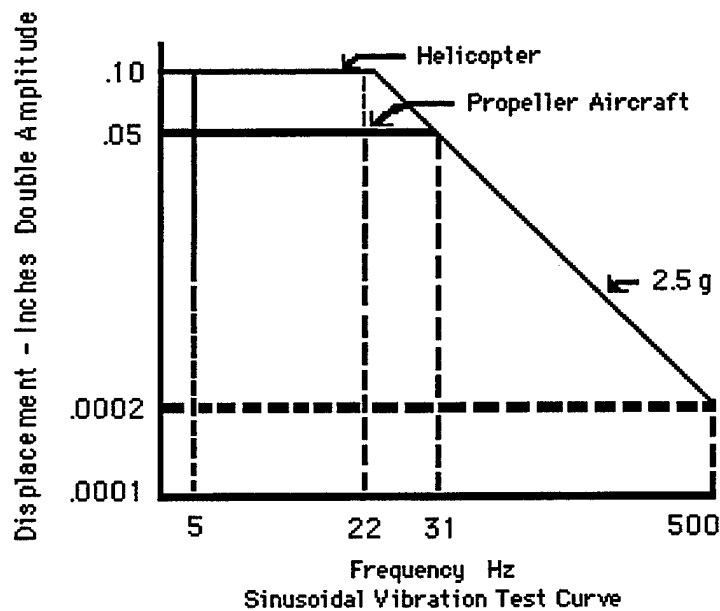


Figure 4. MIL-STD-810E, Category 10, figures 514.4-16 and 514.4-17

ELECTROMAGNETIC COMPATIBILITY

Electromagnetic compatibility testing is a primary concern on USAF aeromedical evacuation aircraft. Safety is the driving factor to assessing the effects of excessive electromagnetic emissions and potential influence on aircraft navigation and communications equipment. Medical devices may be susceptible to fields generated by aircraft equipment and malfunction in their presence.

The EUT was evaluated for compliance with MIL-STD-461D & MIL-STD-462D (7 & 8). ASC/ENAI engineers at Wright-Patterson AFB evaluated the electromagnetic compatibility data and determined the airworthiness of the medical device. Specific tests conducted were as follows:

a. Radiated Emissions (RE-102), "Radiated Emissions, Electric Field, 10 kHz to 18 GHz.": For Air Force aircraft applications, radiated emissions were tested in a narrower range of frequencies from 2 MHz - 1 GHz. This test measured the amount of EMI emitted by the EUT during operation. It verifies the EUT's potential to affect other equipment susceptible to electromagnetic emissions (i.e., aircraft navigation and communications equipment).

b. Conducted Emissions (CE-102), "Conducted Emissions, Power Leads, 10 kHz to 10 MHz.": For Air Force aircraft applications, conducted emissions were tested throughout the entire band of 10 kHz - 10 MHz. This test measured emissions generated by the EUT along its power supply lines. It was performed to assess the EUT's potential to affect other items connected to the same power source, particularly aircraft systems.

c. Radiated Susceptibility (RS-103), "Radiated Susceptibility, Electric Field, 10 kHz to 40 GHz.": For Air Force aircraft applications, radiated susceptibility was tested in a narrower frequency range from 30 MHz - 12.4 GHz at the following field strength levels: 20 V/M below 1 GHz and 60 V/M above 1 GHz (MIL-STD-461D field strength values from Table IV, Category Aircraft Internal). This test evaluated the EUT's resistance to predefined levels of EMI generated by antennas both internal and external to the aircraft.

d. Conducted Susceptibility (CS-101), "Conducted Susceptibility, Power Leads, 30 Hz to 50 kHz.": For Air Force aeromedical aircraft applications, conducted susceptibility was tested throughout the entire frequency band, from 30 Hz to 50 kHz. This test evaluated the EUT's ability to "withstand ripple voltages associated with allowable distortion of power source voltage wave forms."

e. Conducted Susceptibility (CS-114), "Conducted Susceptibility, Bulk Cable Injection, 10 kHz to 400 MHz.": For Air Force aeromedical aircraft applications conducted susceptibility was tested throughout the frequency band from 10 kHz to 200 MHz. This test determined whether "simulated currents that will be developed on platform cabling from electromagnetic fields generated by antenna transmission would affect the equipment under test."

f. Conducted Susceptibility (CS-115), "Conducted Susceptibility, Bulk Cable Injection, Impulse Excitation": This test was performed to ensure the EUT could withstand the "fast rise and fall time that may be present due to platform switching operations and external transient environments such as lightning and electromagnetic pulse."

g. Conducted Susceptibility (CS-116), "Conducted Susceptibility, Damped Sinusoidal Transients, Cables and Power Leads, 10 kHz - 100 MHz," respectively. The "basic concept of this test is to simulate electrical current and voltage waveforms occurring in platforms from excitation of natural resonances." During emissions testing, all EUT's electrical components were operating for the duration of the test to create the worst case emissions scenario. In these tests, the EUT operated in the maximum vacuum mode. For susceptibility testing, the EUT was operated again in the maximum vacuum mode. For both emissions and susceptibility testing, the EUT was tested for operation on 115 VAC / 60, 400 Hz, and internal batteries.

THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS

Extreme temperature and humidity testing determines if aeromedical equipment can be stored and operated during severe environmental conditions without experiencing physical damage or deterioration in performance. (6) Extreme environmental conditions can have incapacitating effects on medical equipment including the following: changes in material characteristics and material dimensions, overheating, changes in lubricant viscosity, changes in electronic components, and electronic or mechanical failures due to rapid water or frost formation.

Testing was conducted in the Armstrong Laboratory's Thermotron Industries, model SM-32 environmental chamber. The EUT was placed in the center of the environmental chamber. All input and output cables and wires were routed through a port in the chamber wall, which was subsequently sealed with a precut sponge plug. The other components of the test setup remained outside the chamber. For operational tests, the EUT was monitored continuously, and a performance check was conducted every 15 minutes. For storage tests, the EUT was placed in the chamber and remained nonoperational throughout the storage portion of the test. The following describes the conditions of the environmental tests performed:

- a. Humidity: $94 \pm 4\%$ RH, $85^{\circ}\text{F} \pm 3.6^{\circ}\text{F}$ ($29.5^{\circ}\text{C} \pm 2^{\circ}\text{C}$) for 4 hr
- b. Hot Temp Operation: $120^{\circ}\text{F} \pm 3.6^{\circ}\text{F}$ ($49^{\circ}\text{C} \pm 2^{\circ}\text{C}$) for 2 hr
- c. Cold Temp Operation: $32^{\circ}\text{F} \pm 7.2^{\circ}\text{F}$ ($0^{\circ}\text{C} \pm 4^{\circ}\text{C}$) for 2 hr
- d. Hot Temp Storage: $140^{\circ}\text{F} \pm 3.6^{\circ}\text{F}$ ($60^{\circ}\text{C} \pm 2^{\circ}\text{C}$) for 6 hr
- e. Cold Temp Storage: $-40^{\circ}\text{F} \pm 3.6^{\circ}\text{F}$ ($-40^{\circ}\text{C} \pm 2^{\circ}\text{C}$) for 6 hr

HYPOBARIC CONDITIONS

Cabin Pressure/Altitude: Altitude testing is critical for aeromedical evacuation equipment due to potential effects of barometric pressure changes on the equipment. A majority of the aircraft characterized as opportune aircraft available for use in aeromedical evacuation, pressurize their cabin atmosphere to barometric pressures equivalent to 8,000-10,000 ft above sea level. The differences in pressures affect the operation of some medical equipment. Altitude testing consisted of operating the EUT while ascending from ground level to 10,000 ft; stopping at 2,000 ft increments for performance checks; and then descending back to ground, at rates of 5,000 ft/min. Descent is stopped at 2,000 ft for performance checks.

Rapid Decompression Testing: A rapid decompression (RD) is the loss of aircraft cabin pressurization and subsequent pressure equalization with ambient atmospheric pressures. It is important to assess medical equipment functioning during and after RD so as not endanger a patient, personnel, or the aircraft itself. The EUT operated inside the rapid decompression test chamber as the chamber was pressurized to an equivalent of 8,000 ft altitude. Then, the chamber altitude was brought to 45,000 ft over a period of 60 seconds, held at 45,000 ft for a few minutes, and then returned to ground at a rate of 10,000-12,000 ft/min. The test was repeated twice more; once for a 7-second RD and once for a 1-second RD. The EUT was monitored throughout the series of decompressions; performance checks were assessed each time the unit returned to ground level.

AIRBORNE PERFORMANCE

Airborne performance evaluations are a cost-effective and invaluable means of validating clinical and operational suitability under actual operating conditions. By carefully evaluating medical equipment items in their proposed operational environment, Aeromedical Research verifies demonstration of all pertinent patient care issues are adequately addressed by the test protocols. Safe and reliable operation is the primary goal of the inflight evaluation and forms the basis for subsequent recommendations to the users.

This phase of testing was conducted by qualified aeromedical crew members from Aeromedical Research on C-141B aeromedical evacuation missions. The EUT was positioned and secured to the aircraft stantion pole and evaluated. Human factors characteristics, securing methods, setup/tear down times and securing locations were also evaluated. Feedback from other aeromedical evacuation crew members participating in delivery of patient care was obtained concerning EUT human factor considerations.

EVALUATION RESULTS

INITIAL INSPECTION

Initial inspection revealed no manufacturing defects. The unit performed to the manufacturer's specification. Electrical safety test results showed all parameters to be within referenced guideline limits. **Battery Performance:** The internal battery ran EUT > 4 hours exceeding manufacturer's specifications. The battery pack can be recharged from the external 115 VAC source in 8 hours.

VIBRATION

The EUT performed according to manufacturers specifications. *Note: as with any pulse oximeter patient movement or vibration of the unit may cause pulse rate and SpO₂ to be erratic and unreadable; therefore, it should be used for trend analysis.

ELECTROMAGNETIC COMPATIBILITY

ASC/ENAI, Wright-Patterson AFB certified the EUT for use in aeromedical evacuation system on all U.S. Air Force aircraft while operating from 115 VAC/60 Hz & battery power. During susceptibility testing EUT experienced an increase in pulse rate from 74 - 83 bpm and an SpO₂ increase from 89 - 94% between a frequency range of 50 Hz - 20.2 kHz. To validate the EUT's operation in this frequency range assessment was done during airborne performance testing. The EUT operated IAW manufacturer's specifications, no unit degradation noted.

THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS

The EUT operated satisfactorily during all five phases of testing. Testing was conducted in the Armstrong Laboratory's Thermotron Industries, model SM-32 Environmental Chamber.

HYPOBARIC CONDITIONS

1. Cabin Pressure/Altitude: The EUT performed in accordance with manufacturer's specifications throughout testing. The unit readings did not waver from baseline parameters of pulse rate 60 bpm and SpO₂ of 98%.
2. Rapid Decompression: The EUT operated satisfactorily following each decompression.

AIRBORNE PERFORMANCE

The inflight evaluation of the EUT was performed on a C-141 aeromedical evacuation mission. Evaluation confirmed that the unit would operate successfully during all phases of flight. Analysis of performance data indicated this unit was easy to enplane and deplane and was compatible with aircraft electrical systems.

SUMMARY

Aeromedical Research found the Ohmeda, Inc., Model 3800 pulse oximeter to be acceptable for use on all U.S. Air Force aeromedical evacuation aircraft while operating on 115 VAC / 60 Hz or battery power. However, during susceptibility testing EUT experienced an increase in pulse rate from 74 - 83 bpm and an SpO₂ increase from 89 - 94% between a frequency range of 50 Hz - 20.2 kHz. To validate the EUT's operation in this frequency range assessment was done during airborne performance testing. The EUT operated IAW manufacturer's specifications, no unit degradation noted. With the above validation complete, further evaluation of the EUT's operation was within expected parameters when subjected to environmental extremes, simulated cabin altitudes, and did not produce a hazard to patient or crew during rapid decompression. The EUT operated IAW manufacturer's specifications, no unit degradation noted. The following recommendations apply:

a. As with any pulse oximeter, patient movement or vibration of the unit may cause pulse rate and SpO₂ to be erratic and unreadable; therefore, it should be used for trend analysis.

*Note: Audible alarms cannot be heard in high noise environments when hearing protection is used. Visually monitor unit during flight.

REFERENCES

1. National Fire Protection Agency (NFPA) 99, Health Care Facilities Code
2. Emergency Care Research Institute (ECRI)
3. AFI 41-203, Electrical Shock Hazards
4. AFI 41-201, Equipment Management in Hospitals
5. MIL-STD 1472, Human Engineering Design Criteria for Military Systems, Equipment, and Facilities.
6. MIL-STD 810E, Environmental Test Methods and Engineering Guidelines.
7. MIL-STD 461D, Electromagnetic Emission and Susceptibility Requirements for the Control of Electromagnetic Interference.
8. MIL-STD-462 D, Measurement of EMI Characteristics.
9. Ohmeda, Inc., Model 3800, Pulse Oximeter, Operators Manual.
10. Aeromedical Research Procedures Guide, Internal Operating Instruction, Systems Research Branch, Armstrong Laboratory.

APPENDIX
MANUFACTURER'S SPECIFICATIONS OF
OHMEDA, INC., MODEL 3800, PULSE OXIMETER

SPECIFICATIONS

General

Size	3.7 in. H. x 9.53 in. W. x 8.86 in. D.
Weight	2.23 kg. (4.92 lb.)
Power	15 watts/0.2 amps, 100/120 VAC 60 Hz and a pack of four, 2.5 amp hour, 2-volt Sealed Lead-acid batteries.
Environmental	Temperature: 0°C to 50°C (operating). -40°C to 70°C (storage and shipping). Humidity: 5 - 95% Atmospheric Pressure: 0 to 10,000 ft above sea level